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Art Unit 3627
U.S. Patent and Trademark Office

FAX NUMBER: (571) 273-8300

DATE: August 25, 2006

SENDER: Ralph E. Jocke, Esq.

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COMMENTS: Attached is Applicants' Response to the Office Action dated August 16, 2006. Please refer to the following.

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August 25, 2006

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Attn: Art Unit 3627
Patent Examiner Garcia Ade

Re: **Application Serial No.:** 09/849,625
Confirmation No.: 9504
Applicants: McGrady, et al.
Title: Method of Tracking and Dispensing Medical
Items
Docket No.: D-1137

Sir:

Please find enclosed Applicants' Response to the Office Action dated August 16, 2006 for filing in the above identified Application.

No fee is deemed required. However, the Commissioner is authorized to charge any necessary fee associated with this Response and any other fee due to Deposit Account 10-0637.

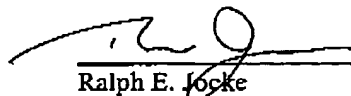
Very truly yours,



Ralph E. Jocke
Reg. No. 31,029

TRANSMISSION CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(b) AND 1.6(d)

I hereby certify that, on the date shown below, this document and the documents indicated as enclosed herewith are being sent by facsimile transmission to the U.S. Patent and Trademark Office at (571) 273-8300.

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AUG 26 2006

D-1137

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
McGrady, et al.)	
)	
Application No.: 09/849,625)	Art Unit 3627
)	
Confirmation No.: 9504)	
)	
Filed: May 4, 2001)	Patent Examiner
)	Garcia Ade
)	
Title: Method of Tracking and)	
Dispensing Medical Items)	

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Request For Clarification

Applicants request clarification of the record in response to the Office Action ("Action")
dated August 16, 2006.

The Time Period for Reply

The Action sets forth no time period for reply. Unless otherwise stated on the record, Applicants will presume the time period to reply is unlimited (if reply is even necessary). Clarification is requested.

The Pending Claims

The Action does not correspond to the pending claims. The Action (on page 2) mentions claims 1-21. However, the Office's assessment of the pending claims does not match that of the application file. As best understood, the Action is directed to an application other than Applicants'. Clarification is requested.

The Restriction Requirement

As the Action appears directed to an application other than Applicants', the alleged restriction requirement is deemed moot.

Nevertheless, even if the restriction requirement were somehow legally proper (which it isn't), the restriction requirement is traversed. The restriction requirement is legally improper. Withdrawal of the restriction requirement (as best understood) is respectfully requested.

The Restriction Requirement is not legally proper because it is not timely

The lengthy prosecution history is evidence that there never was a "need" for a restriction requirement from initial filing through the current Action. It follows that the "soon as the need" (MPEP § 811) time period for making a restriction requirement has expired. Thus, the requirement is not legally proper and should be withdrawn.

Furthermore, the Office's repetitive and unsupported allegations of a need for restriction appear to be an effort to deny Appellants judicial review of the refusal to grant their application. If true, this constitutes an abuse of agency authority. Such actions violate the Administrative Procedures Act, 5 U.S.C. § 701 *et seq.* Such agency action also violates the fundamental legal principle that an administrative agency may not avoid review of its actions by engaging in repetitive activity which does not remain in place long enough to enable judicial review.

Southern Pacific Terminal Co. v. Interstate Commerce Com., 219 U.S. 498, 55 L.Ed. 310, 31 S. Cr. 279 (1911).

The Restriction Requirement is not legally proper because there is no serious burden

MPEP § 803 sets forth criteria for a proper election requirement. One of the criteria is that there must be a serious burden on the Examiner in order for election to be required. Conversely, if the search and examination of an entire application can be made without serious burden on an Examiner, then it must be examined on the merits (which has already occurred). As discussed in more detail hereinafter, as the application has already received numerous complete actions on the merits, the criteria for establishing serious burden has not been met.

The fact that numerous examinations on the merits has already occurred is *prima facie* evidence that there is no serious burden. Appellants respectfully submit that the requirement is not legally proper because the criteria for serious burden has not been met. Rather, the lengthy prosecution history evidence is in direct conflict with the sudden allegation of serious burden. The application has *already* been searched, there has *already* been numerous examinations of the recited subject matter, and these examinations were on the merits. The claims corresponding to each of the alleged inventions were already fully examined. How can the current Examiner

allege that the burden to examine the application is too hard when the prior Examiners have already easily performed complete actions on the merits?

Contrary to the current Examiner's opinion, (by inference) the prior Examiners (e.g., Steven McAllister and Bryan Jaketic) assigned to this application concluded that there was no need of restriction requirement. Hopefully, the Actions of these prior Examiners were "complete as to all matters" in accordance with 37 C.F.R. 1.104(b). Further, the standards of examination "must be the same throughout the Office" (MPEP § 706(I)). Thus, the prior Examiners' conclusions of no need for an election requirement constitutes a final appropriate determination. Otherwise, the Office is admitting on the record that all of the previous Office Actions by the prior Examiners did not meet the examination standard of the Office. Is the Office admitting that it did not previously conduct a proper handling of this application (which necessitated needless Responses by Applicants thereto)? Also, all of the Office Actions have come from the same Art Unit. Is the Office admitting that the examination standard of that Art Unit freely changes?

The Office has no legal basis for election requirement just because an application was reassigned to yet another Examiner, especially in the same Art Unit, as is the current situation. Again, this would violate the Office's requirement for applying a same standard of examination. Applicants request that the application be returned to a previous Examiner (who disagrees with the current Examiner's assessment of serious burden).

The fact remains, the application was already fully acted upon, the recited subject matter was already fully examined, and the application has already received multiple complete actions on the merits. As the prosecution history shows, this application has received numerous Office Actions. An Art Unit is not authorized to use application reassignment as an excuse to

circumvent the rules and Office procedures. Unless the Office has a newly stated policy of causing needless responses by Applicants to complete actions on the merits before first applying a restriction election requirement, then the requirement by the current Examiner is clearly arbitrary and capricious.

The Office has not shown the alleged subcombinations I, II, III to be distinct

The burden is on the Examiner to provide valid examples. If Applicants prove or provide an argument that the Examiner's suggested other use cannot be accomplished or is unreasonable, then the burden is on the Examiner to document a viable alternative use or withdraw the requirement. MPEP 806.05 (d). Applicants respectfully submit that the Office has not met its required burden. Each separate utility alleged by the Office is unreasonable, as discussed herein.

The Action also has not provided the required showing of distinct subcombinations. The Action has not provided a showing that the alleged subcombinations do not overlap in scope, are not obvious variants, and are separately usable. For example, the Office has not shown that each alleged subcombination has separate utility. The Office misinterprets and misapplies the meaning of "separately usable".

The alleged subcombination I

The alleged subcombination I is directed to a method. The alleged separate utility is unreasonable because it is not a method but rather an apparatus. The Office's reliance on an apparatus for separate utility of a method is unreasonable and legally improper.

Furthermore, the Action also has not shown that the alleged subcombinations II and III cannot be used with "medication depots and other smart storage location on a real-time basis" (i.e., the provided separate utility of alleged subcombination I). That is, the Action has not

shown that the alleged subcombinations II and III are prevented from being used with "medication depots and other smart storage location on a real-time basis". Thus, the Office has not shown alleged subcombinations II and III to be distinct from alleged subcombination I.

Additionally, the Office has not explained how "taking a first type of medical item from first location" (the alleged subcombination I) is distinct from the "removing a quantity of the first type of medical item from at least one location" of alleged subcombination II (e.g., claim 15 at step g) or the "quantity of a first type of medical item from" of alleged subcombination III (e.g., claim 19 at step a).

The alleged subcombination II

The Action also has not shown that the alleged subcombinations I and III are prevented from being used to achieve the utility of "controlling the ordering, dispensing, and administration of medical items" (i.e., the provided separate utility of alleged subcombination II). Thus, the Office has not shown the alleged subcombinations I and III to be distinct from the alleged subcombination II.

The alleged subcombination III

The alleged subcombination III is directed to a method. The alleged separate utility is unreasonable because it is not a method but rather an apparatus. The Office's reliance on an apparatus for separate utility of a method is unreasonable and legally improper.

Additionally, the Action also has not shown that the alleged subcombinations I and II are prevented from being used with "an intensive care treatment location" (i.e., the provided separate utility of alleged subcombination III). Thus, the Office has not shown the alleged subcombinations I and II to be distinct from the alleged subcombination III.

The Restriction Requirement Is Without Legal Basis

Appellants also respectfully wish to point out that the Action fails to state a legally sufficient basis for imposing a restriction requirement. The Action indicates that the restriction requirement is solely based on a showing of the alleged inventions being "distinct." The statutory authority for the Patent Office to impose a restriction requirement is found in 35 U.S.C. § 121. The statute expressly states that before the Patent Office may require restriction, the inventions must be both "independent" and "distinct." The regulations that have been promulgated pursuant to this statute, 37 C.F.R. § 1.141 and 37 C.F.R. § 1.142, both expressly state that before a restriction requirement may be imposed the inventions claimed must be both independent and distinct.

In the Action, there are only unsupported assertions that the sets of claims are "distinct." There are no assertions that the sets of claims are "independent", as is required. This standard does not comply with the statutory requirements. Therefore, the standard used in the Action for seeking to impose a restriction requirement is legally incorrect due to noncompliance with the clear wording of both the statute and the regulations promulgated thereunder. The application of such an incorrect legal standard is arbitrary, capricious, and contrary to law in violation of the Administrative Procedures Act.

Furthermore the Patent Office has acknowledged that before claimed inventions can be considered to be "independent" the inventions must be unconnected in design, operation, or effect. MPEP § 802.01. The Office has not shown that the claims directed to Appellants' invention are unrelated in design, operation, and effect. Thus, the statutory requirements are not met and no restriction requirement may be imposed.


Rejoinder

The Action has not addressed the issue of rejoinder of claims (MPEP § 821.04). Applicants respectfully submit that even if the Office were to somehow show (which it hasn't) restrictable claims as alleged, that process claims would be entitled to rejoinder. Applicants reserve all rights to rejoinder.

Conclusion

For all the foregoing reasons it is respectfully submitted that there is no valid basis for the restriction election requirement. Applicants respectfully request that the requirement be withdrawn. If necessary, Appellants provisionally elect Group I with traverse.

Respectfully submitted,



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